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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/656,034

09/05/2003

James Hunter Boone

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11/21/2005

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EXAMINER

VENCI, DAVID J

ART UNIT

PAPER NUMBER

1641

DATE MAILED: 11/21/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No. 10/656,034	Applicant(s) BOONE ET AL.	
	Examiner David J. Venci	Art Unit 1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on August 19, 2005.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-14 and 17-24 is/are pending in the application.
- 4a) Of the above claim(s) 4, 5 and 19 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-3, 6-14, 17, 18 and 20-24 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-14 and 17-24 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

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### **DETAILED ACTION**

Examiner acknowledges Applicants' reply, filed August 19, 2005, which amended claims 10-14, 17, 20 and 24, and cancelled claim 25. Currently, claims 1-3, 6-14, 17-18 and 20-24 are under examination.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

### ***Specification***

The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Examiner is unable to locate antecedent support for the following subject matter of claims 8-9, 11 and 22-23:

The step(s) required in the process of "contacting the sample... to create a treated sample".

The step(s) required in the process of "contacting the treated sample... to create a readable sample".

Correction is required.

***Claim Rejections - 35 USC § 112***

Claims 2-3, 8-13, 17-18 and 20-24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claims 2 and 17, the recitation of permissive language "may be" is indefinite. Whether claim language preceding or subsequent to "may be" contains required claim limitations is not clear.

In claims 2, 12 and 17, the recitation of the term "substantially" is indefinite. The term "substantially" is not defined by the claim and the specification does not provide a standard for ascertaining the requisite degree. One of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

In claims 2, 12 and 17, the passive voice recitation "may be substantially concluded" is indefinite because the identity of object(s) and/or step(s), if any, required for performing conclusion, or achieving a state of conclusion, is/are not clear.

In claims 6 and 20, the recitation of "total anti-neutrophil cytoplasmic antibodies" is indefinite. Whether/how the noun "antibodies" is modified by the adjective "total" is not clear.

In claims 8, 11 and 22, the recitation of "the sample with neutrophil cytoplasmic antigens" lacks antecedent basis.

In claims 8, 11 and 22, the identity of step(s) required in the process of "contacting the sample... to create a treated sample" is not clear and lack antecedent support in the specification.

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In claims 9, 11 and 23, the recitation of "the treated sample with polyvalent antibodies" lacks antecedent basis.

In claims 9, 11 and 23, the identity of step(s) required in the process of "contacting the treated sample... to create a readable sample" is not clear and lack antecedent support in the specification.

In claim 8-9, 11 and 22-23, the recitation of the infinitive "to create" is indefinite. Whether the act or process of creating is completed or performed, or merely intended, is not clear.

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***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-3, 6-7, 14, 17-18 and 20-21 are rejected under 35 U.S.C. 102(e) as being anticipated by Fine (US 6,667,160).

Fine describes an method for testing a fecal sample comprising obtaining a fecal sample (see Abstract, "stool samples"), and determining whether anti-neutrophil cytoplasmic antibodies are present (see Table 1, "ATTA – antitissue transglutaminase antibody").

With respect to claim 2, Fine describes a diagnosis of colitis (see Abstract, "colitis").

With respect to claims 3 and 18, the language "used to aid in the differentiation of ulcerative colitis from Crohn's disease" is not afforded patentable weight because the language is interpreted as a statement that merely states an intended use of the claimed invention.

With respect to claims 6 and 20, notwithstanding issues of indefiniteness of the phrase "total anti-neutrophil cytoplasmic antibodies" addressed under *Claim Rejections - 35 USC § 112, supra*, Examiner posits that Fine describes a fecal sample (see Abstract, "stool samples") that necessarily contains "total anti-neutrophil cytoplasmic antibodies", and would be so recognized by persons of ordinary skill.

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With respect to claims 7 and 21, Fine describes diluting a fecal sample (see col. 6, line 43, "gluten ingestion").

With respect to claim 14, Fine describes an ELISA (see col. 14, line 28).

***Response to Arguments***

In prior Office Action, claims 6 and 20 were rejected under 35 U.S.C. 112, second paragraph, as being indefinite for the recitation of "the total". Specifically, whether/how the noun "antibodies" is modified by the adjective "total" is not clear. In response, Applicants argue that the term "total" is intended to describe "the complete anti-neutrophil cytoplasmic antibodies... that may occur in the gut following protease and acid digestion" (see Applicants' reply, p. 9, first full paragraph). Applicants' argument has been carefully considered but is not persuasive because Applicants' argumentation providing a description of a "complete anti-neutrophil cytoplasmic antibodies" does not appear in the specification, as originally filed. Whether/how the noun "antibodies" is modified by the adjective "complete" is not clear.

In prior Office Action, claims 1-3, 6-14, 17-18 and 20-25 were rejected under 35 USC 103(a) as being unpatentable over Walsh & Rose (US 6,218,129) in view of Padron (US 5,359,083). Applicants' argumentation is fully persuasive and sufficient to overcome this rejection. Accordingly, this rejection is withdrawn.



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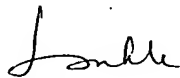
**Conclusion**

No claims are allowed at this time.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David J. Venci whose telephone number is 571-272-2879. The examiner can normally be reached on 08:00 - 16:30 (EST). If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

David J Venci  
Examiner  
Art Unit 1641

djv



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11/10/05